

**FOOD AND DRUG ADMINISTRATION (FDA)**  
*Center for Drug Evaluation and Research (CDER)*  
*Gastrointestinal Drugs Advisory Committee (GIDAC)*  
*Hilton Washington DC/North, Gaithersburg, MD*  
*November 5, 2010*

**Draft Questions to the Committee**

1. Is the pathophysiology of GERD the same in patients ages 1 month to less than one year and adults? Please discuss.
2. When acid suppressing agents are approved for symptomatic GERD in adults, should studies in pediatric patients ages 1 month to less than 1 year be required? Please discuss.
3. Is there a population of infants that should be studied in future clinical trials of acid suppressing agents? Please discuss.

If you answered yes, please respond to the following questions:

- a. How would this population be identified?
  - b. What primary endpoint should be studied? What assessment tools (pH-metry, endoscopy, impedance, survey instruments) would you recommend to assess the primary endpoint?
  - c. What design should be used? Please comment on duration of treatment and the roles of enrichment, withdrawal, and concomitant therapies (H<sub>2</sub> blockers, antacids, conservative measures).
4. Are your recommendations in response to the questions above applicable to the neonatal and premature infant population? Please discuss.
  5. In what indications other than GERD in patients 1 month to less than 1 year might acid suppressing agents have a therapeutic role? Please discuss.